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TRENDS IN COMPARATIVE EFFECTIVENESS OF TOP 20 HIGHEST SELLING DRUGS

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OBJECTIVES: The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of $1.1 Billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$160B worldwide sales) **METHODS:** Drugs were categorized as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. Cost effectiveness Ratios (CERs) published in peer-reviewed journals and technology assessments conducted by payers were used for this analysis. **RESULTS:** There is a large variability in CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. For example, CERs for clopidogrel range from $13,000 to $32,000, whereas for bevacizumab, it ranged from $125,000 to $350,000. Most striking was the CER for epotein alpha, which was ~$55,000 for Hb target levels of 11.0–12.0 g, but increased dramatically to $613,015 for target Hb of 12.0–12.5 g. Our analysis of 'generic alternatives' and the 'new clinical evidence' shows that previously deemed cost effective drugs could be re-assessed as being not cost effective when generics or new branded drugs with comparable efficacy become available (e.g. CATIE trial data for quetiapine). This would play a major role in the future, as more payers, including the US public payer CMS, explore ways to design a continuum in the coverage decision making process; implying that updated cost effectiveness ratios could change previously established coverage policies. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

PHP60

PRICING AND REIMBURSEMENT (P&R) IN BRIC COUNTRIES

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OBJECTIVES: To review the procedure and requirements for P&R of pharmaceuticals in Brazil, Russia, India and China. **METHODS:** A review was conducted of the official websites of governmental and public health institutions in the countries of interest. This review was complemented by interviews with key stakeholders in the respective countries. **RESULTS:** Free pricing of pharmaceuticals exist in general terms in Russia and India. In India, free pricing applies to non-scheduled drugs and pricing restrictions may be extended to drugs on the National Essential Medicines List. In China, prices are fixed by central government; whereas in Brazil external drug pricing is used as the major cost-containment measure. In Brazil, hospital drugs are reimbursed if they are on the Essential Medicines List and expensive therapies for cancer and chronic diseases are provided by the Exceptional Medicines Program. Reimbursement of retail drugs is limited to the Popular Pharmacy Program and the majority of costs are covered out of pocket. Similarly, the most drugs costs are covered out of pocket in India; with only established generics being reimbursed. Russia saw the federal reimbursement system, DLO, being introduced in 2005 to provide pensioners, invalids, and patients suffering from chronic diseases access to new therapies. In 2008 the DLO program was split into two subprograms: the expensive medicines program covering seven indications, with the remaining drugs on the DLO list being supplied through the ONLS program. In China, innovative drugs are currently negotiated at local level. **CONCLUSIONS:** Although cost-containment measures seen with more traditional markets are prevalent in the emerging markets, these markets are still undergoing significant changes in their P&R frameworks. Thus, as these markets develop their processes further, it will be necessary not only to consider P&R in the context of conventional wisdoms but also the political, social and cultural norms underpinning these systems.

PHP61

POSITIVE DRUG LIST IN BULGARIA—5 YEARS LATER

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OBJECTIVES: To compare the regulatory framework and the structure of the Positive Drug Lists (PDL) in Bulgaria issued in 2003 and 2009. **METHODS:** Comparative legislation analysis was applied towards the requirements of the newly adopted regulation on PDL in 2008 with the regulation in 2003. It was analysed the requirement to the applicants, including the pharmacoeconomic evidences, selection procedure and the structure of the PDL. **RESULTS:** Main changes in PDL regulation are the following. In 2003 PDL the medicines were selected according to their innovativeness in one list under INN. In 2008 PDL medicines were separated in 4 lists according to the financing sources—Health Insurance, Hospital, Governmental budget and National Health programs. The criteria for the medicines evaluation were increased (efficacy, effectiveness, safety and pharmacoeconomic) and detailed in the new regulation. The PDL Committee is deciding both reimbursement status and level. The reimbursement level is defined on the basis of the international comparison with reimbursement levels in 7 reference countries calculated as lowest cost per DDD per unit. The changes in the structure of the PDL are the following. In 2003 there were list A with 625 INNs and list B with trade names that were updated on a yearly basis. In 2009 the four separated lists include 575 INNs presented with their trade names and dosage forms together. Reimbursement list 1 include 289 INNs, list 2 (518 INNs), list 3 (101 INNs) and list 4–59 INNs. Lots of INNs in all lists are overlapping. Also near 50 combinations are presented in the PDL. **CONCLUSIONS:** The new PDL includes less INNs as a total number and lots are overlapping between the lists. No National pharmacoeconomic guideline exists both for the PDL committee and manufacturers and thus no evidences for the influence of pharmacoeconomics exist.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP62

FREE BUT VALUABLE: THE ECONOMIC SIGNIFICANCE OF SERVICES PROVIDED BY PORTUGUESE PHARMACIES

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OBJECTIVES: Besides dispensing medicines, pharmacies render other services including advice on health problems and on the best use of medicines; detecting problems in patients' medications; counseling on nutrition, etc. The majority of these services is free. Up to now, the volume of these services in Portugal were unknown. This paper presents 2008 estimates for the volume of pharmacy interventions and their economic value. **METHODS:** The data came from two 2008 surveys. A pharmacy survey was designed to estimate the volume and cost of the free interventions in community pharmacies in Portugal. In a general population survey, respondents answered a set of questions (choice experiments) designed to elicit their willingness to pay for a few typical services provided for free at community pharmacies. **RESULTS:** We estimate a total of 38.8 million free pharmacy interventions in 2008, 3.7 interventions per inhabitant. The top three pharmacy interventions were advice on non-prescription medicines, advice on prescription-only medicines and counseling related to point-of-care measurements and monitoring (cholesterol, pregnancy, etc.) and they used 2.8 million hours of work, about 13% of the total hours of work, at a cost of €54 million. This cost was equivalent to 20% of the pharmacies' gross income. We estimated the willingness to pay for the three main pharmacy interventions by conjoint analysis. The aggregate value of the services provided was estimated at €76.5 million. The net value, from society's perspective, for the three interventions was estimated to be €51 million. **CONCLUSIONS:** We found the volume of services provided at no charge to be significant, as were the resulting pharmacies' costs. The benefits to consumers were even larger generating a substantial net benefit to society.

PHP63

CONSENSUS OF KEY DECISION MAKERS AND EXPERTS ON THE PRESENT AND FUTURE ON THE ASSESSMENT OF HEALTH TECHNOLOGIES IN SPAIN

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OBJECTIVES: Mechanisms for assessing health technologies (HT) have gone through major regulatory changes over the last five years in Spain. This study aims to determine the consensus level amongst decision makers and experts on the present and future of health technologies' assessment. **METHODS:** This is the second part of a two-phase study. A sample of participants and experts in HT evaluation was invited to participate on a two-round Delphi consultation (phase 2) about the most relevant and controversial issues identified in phase I. The present situation as well as desirable (D) and feasible (P) feature scenarios were considered. Consensus was reached when given statements were scored 7.5 or higher by 75% or more of the participants. **RESULTS:** Decision makers (n = 16) and experts (n = 8) participated in the study (mean involvement length in HT assessment: 12.4 [SD: 7.7] years). Present: Consensus was reached on that 1) the absence of established mechanisms to set priorities and define needs (83.3%), and the scarce political support (79.2%) explain the little influence of current legislation on HT implementation; 2) safety and efficacy (79.2%) are always considered to decide the implementation of HT. Coincidence of opinions existed for the poor definition of decision makers' roles and responsibilities (70.8%) and the deficient management of information between evaluation entities and decision makers (62.5%). Future: 1) Importance of value dossier and impact budget estimates (D: 95.8%, P: 12.5%) to support implementation; 2) efficiency and cost-effectiveness data will determine decisions (D: 91.7%; P: 12.5); 3) benefits for patients (D: 87.5%; P: 41.7%) and equity improvements (D: 91.7%; P: 16.7%) will be prioritised; 4) gains on patients' satisfaction, preferences and health related quality of life (HRQL) will deserve special attention (D: 75%; P: 12.5%) **CONCLUSIONS:** An important gap exists between desirable (D) and feasible (P) future scenarios. Agreement upon implementation mechanisms is mandatory. Patient centred results become relevant.

PHP64

QUALITY ADJUSTED LIFE YEARS (QALYS) IN ECONOMIC EVALUATIONS OF HEALTH TECHNOLOGIES IN SPAIN: A REVIEW OF THE 2003–2009 LITERATURE

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OBJECTIVES: To appraise economic evaluations of health technologies that included QALYs as an outcome measure conducted over the last seven years in Spain. **METHODS:** Economic evaluations that included QALYs as an outcome measure,

conducted in Spain and published between January, 2003 and April, 2009 were identified. A combination of terms was applied to systematically review electronic and grey literature sources. Three Spanish journals were hand searched. Methodological quality was assessed applying the National Institute of Clinical Excellence (NICE) 10 criteria checklist and the Oxford Centre for Evidence Based Medicine (CEBM) recommendations for appraising economic evaluations. **RESULTS:** After applying the inclusion and exclusion criteria, a total of 48 papers and 1 Health Technologies Evaluation Agency (HTEAs) report were included. Key findings: 1) 69.5% of papers referred to therapeutic interventions; 30.4% to preventive strategies; 2) no assessments of diagnostic procedures were identified; 3)10.4% dealt with medical devices; 4) Markov modelling was frequently applied (58.7%); 5) the NHS perspective was commonly adopted (56.5%); 6) costs and effects were usually discounted (71.7%); 7) probabilistic methods were reported in 36.4% papers; 8) in 91.9%, either the ICER or ICUR was stated; 9) effectiveness, costs and utility data came from Spanish sources in 15.2% publications; 10) 60.8% of studies were of 3b level of evidence mainly due to the diverse nature of the sources consulted to gather data, estimate utilities and design models; 11) 89% of authors compared their findings against an accepted threshold of €30,000 per QALY, but little attention was given to contrasting results or addressing other implementation issues; 12) 45.6% reported the source of funds. **CONCLUSIONS:** A small number of economic evaluations using QALYs was conducted. Diagnostic and preventive interventions as well as medical devices were scarcely considered. Low evidence scores show that important methodological limitations remain unsolved to produce reliable estimates to guide the allocation of resources.

PHP65

PUBLICATION OF COST-EFFECTIVENESS ANALYSES AND SUBSEQUENT CITATIONS IN THE MEDICAL AND HEALTH ECONOMICS LITERATURE

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OBJECTIVES: The dissemination of research findings begins with publication in peer-reviewed journals and is continued by citation of the original study in other publications. The number of citations received by an article is one marker of study importance. We investigate whether the proliferation of the cost-effectiveness analysis (CEA) literature in recent years is matched by increased citations of study results. **METHODS:** We used the Tufts Medical Center registry of original CEAs published through 2006 (www.cearegistry.org) (N = 1394) to determine the journal name, and year of publication. We used the Science Citation Index Expanded (ISI Web of Knowledge, Thomson Reuters) to determine the extent to which each CEA has been cited in other publications. To control for different publication times, we calculated for each article the mean number of citations per year since study publication. **RESULTS:** Citation information was available for 1,301 studies (94% of studies analyzed). The average (SD) number of citation counts per article was 26 (± 37) (range 0 to 391) and the average (SD) number of citations per year since article publication was 3.4 (± 3.9) (range 0 to 34) and did not vary substantially by year of publication. The ten most cited CEAs by number of citations per year since publication were in high profile medical journals (e.g., Lancet, New England Journal of Medicine) and were frequently co-authored by the most prolific authors of cost-effectiveness research. These studies pertained mainly to coronary stents, implantable defibrillators, HPV vaccination, screening and treatment for HIV positive patients. **CONCLUSIONS:** CEAs are widely published and cited, but this phenomenon is not yet accompanied by an increase in citations. Further analyses is needed to analyze factors that may contribute to citation of CEAs, as well as measures to enhance better dissemination of this important body of research to researchers and decision-makers.

PHP66

COST-EFFECTIVENESS RESEARCH ON PREVENTIVE MEASURES: A SURVEY OF THE PUBLICATIONS IN 2008

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OBJECTIVES: In recent years the literature regarding the cost-effectiveness of disease prevention and health promotion has grown exponentially. Aim of this study is an analysis of published economic evaluations on prevention: (i) how many economic evaluations are published (ii) what type of economic evaluations are published (cost-effectiveness analyses, cost-utility analyses or cost benefit analysis) (iii) which diseases or health problems (WHO-ICD-10 chapters) do economic evaluations of preventive interventions focus on (iv) how do those diseases or health problems relate to the burden of disease in the Netherlands? and (v) how cost-effective is prevention? **METHODS:** Economic evaluations on preventive measures were identified by searching PubMed and Scopus. **RESULTS:** In the calendar year 2008, 232 economic evaluations of preventive interventions are published. In 114 studies the QALY is used as outcome measure, in 46 LYS is used and 15 studies present both QALY and LYS. In 38 studies the outcome measure is 'cases prevented'. Most economic evaluations focus on the prevention of infectious diseases (73), cancers (49), cardiovascular diseases (23) and psychological- and behaviour disorders (16). Cardiovascular diseases are responsible for the highest burden of disease (12.5%), followed by psychological- and behaviour disorders (11.5%). Of the cost-utility evaluations 84% show an incremental cost-effectiveness ratio (ICER) below €50,000 per QALY, of the cost-effectiveness evaluations almost 80% show an ICER below €50,000 per LYS. **CONCLUSIONS:** This study shows the disease clusters for which most preventive economic evaluations are published, and whether this corresponds with the diseases which cause much burden of disease and how cost-effective preventive interventions are. The conclusion of our study is that the published economic evaluations correspond rather well with the burden of disease in The Netherlands, with exception of infectious diseases and cancers. Finally, it appears that almost all published economic evaluations of preventive measures show favourable cost-effectiveness levels.

PHP67

THE PROBLEM-BASED LEARNING AS A NEW PRACTICAL METHOD OF SKILL DEVELOPMENT IN THE HEALTH SCIENCES HIGHER EDUCATION

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OBJECTIVES: The last decade has witnessed a rapid expansion of biomedical knowledge. Despite this, fashions in medical education over the same period have shifted away from factual (didactic) teaching and towards contextual, or problem-based, learning (PBL). This paradigm shift has been justified by studies showing that PBL improves reasoning and communication while being associated with few if any detectable knowledge deficits. **METHODS:** A retrospective and comparative analytical approach was used. Data on final Cardiopulmonary Resuscitation (CPR) exam grades, collected from PBL or traditionally trained students, and on teaching process, were obtained for a total of 2220 students. The data collection took place between 2003–2008, in two major locations in Hungary and in Finland. The data analysis was done with Chi-square and ANOVA using SPSS14.0. PBL and traditional teaching methods were compared as well as the schools themselves. **RESULTS:** Students who received PBL training had better final CPR exam grades than traditionally trained peers. T-test on means yielded significant differences ($t = 3569$; $p < 0.001$) between PBL and conventional training favouring PBL taught students. The only significant difference among universities was found for PBL training. There was no difference between the two universities in terms of final CPR grades when traditional training was concerned. **CONCLUSIONS:** It is possible to indicate significant differences in the perception of the development of problem solving skills between the two countries with the help of the khi square trial (khi2 = 17,974 f = 3 $p < 0.01$). The Finnish evaluated the efficiency of this method, in regard to developing problem solving skills, considerably higher than their Hungarian peers. One of the new and important messages of the study is to emphasise that the process of learning will not extend in one dimension for the whole life, and it will not confined just for the formal school education.

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FIRST IMPRESSIONS FROM A SHORT TRAINING COURSE IN RATIONAL USE OF DRUGS FOR THE PHARMACOLOGISTS IN THE PHARMACY SCHOOLS IN TURKEY

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OBJECTIVES: Pharmacist' role as patient counsellor/educator in the ambulatory settings is essential for the rational use of drugs (RUD). The need for the qualified pharmacy services enforce improvement of teaching methods in pharmacotherapy. Pharmacy students often face problems in implementing theorical pharmacotherapy knowledge to practice. Thus, novel methods (e.g. Groningen model) are developed for pharmacotherapy teaching. **METHODS:** A short course of "RUD Teaching" was conducted. Fifteen pharmacologists from 8 different pharmacy schools (of the total 13) have attended the 4 day training course. On the first day, attendants were subjected to a pretest which was based on the evaluation of their dispensing attitudes. For this purpose a simulated patient presented a prescription ordering a single drug for the treatment of his ailment. Attendants had a 3 day training similar to the Groningen model and finally they were subjected to a posttest. On the last day, trained attendants were expected to put their experience into practice with 12 pharmacy students. **RESULTS:** The results have shown that the average dispensing score of the 15 trainees (pharmacologists who received the training) which was 32/100 in the pretest, was increased to 72/100 at the end of the three days training. The questionnaire showed that all of the pharmacology lecturers agreed that the novel teaching method would improve the learning efficiency and communication skills of the student and change their dispensing attitude. On the otherhand 41.6% have stated that they believed the new teaching method would produce extra workload to their department. However, all of them have claimed that they would practice the new method in their departments. Also, the students have also stated that the course improved their dispensing skills. **CONCLUSIONS:** Although the course was conducted with a small group of trainees, results show that Groningen model can be adapted to RUD teaching in the Turkish pharmacy schools.

HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs

PHP69

DOES THE PROCEDURE MATTER? DIFFERENCES IN THE FUNDING OF DRUGS AND MEDICAL SERVICES IN AUSTRALIA

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OBJECTIVES: The aim of this study was to explore the views and perceptions of stakeholder's about the current national health technology assessment process for new